

K965005

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11.5 510(k) Summary

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Name of the Device:

Proprietary name:	lamin® Impregnated Gauze Dressing
Common name:	Hydrogel Dressing
Classification name:	Hydrogel and Burn Dressing

Identification of Predicate Devices to which Substantial Equivalence is Being Claimed:

lamin® Impregnated Gauze Dressing is substantially equivalent in function and intended use to the following non-classified commercially available non-interactive wound and burn dressings:

Dermagran Wound Dressing
SteriCare Hydrogel Gauze Dressing
CarraGauze Hydrogel Wound Dressing
lamin Hydrating Gel

Device Description:

Explanation of how the device functions: lamin® Impregnated Gauze Dressing acts to provide a moist wound environment and protect the wound.

Basic scientific concepts that form the basis for the device: lamin® Impregnated Gauze Dressing was designed to provide a soothing, moist environment for each application to various types of wounds as an impregnated gauze dressing.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: lamin® Impregnated Gauze Dressing is sterile impregnated cotton-blend non-woven gauze.

Statement of the Intended Use of the Device, Including General Description of the Conditions the Device Will Mitigate and the Patient Population for which the Device Is Intended: An impregnated hydrogel for the dressing and management lamin Impregnated Gauze Dressing is intended to be used for the dressing and management of pressure ulcers (stage I-IV), diabetic ulcers, stasis ulcers, 1st and 2nd degree burns, arterial ulcers, pressure sores, cuts, abrasions, irritations of the skin, and skin conditions associated with peristomal care. The dressing is intended to cover a wound or burn on a patient's skin, provide a moist wound environment and protect against abrasion, friction, desiccation, and contamination.

These indication statements are not different from the predicate devices identified above.

Statement of how the Technological Characteristics of the Device Compare to those of the Predicate Device: The technological characteristics of the device such as form, absorptive ability, occlusion, conformability, sterility, moist wound healing and appearance are not different from the predicate devices cited.

Assessment of Performance Data: Biocompatibility testing has been performed as recommended in the "Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing." These tests support the safe use of lamin[®] Impregnated Gauze Dressing as a temporary dressing in contact with breached or compromised skin.